NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BIOGEN '755 PATENT LITIGATION	**Civil Action No.: 10-2734 (CCC)(JBC) (consolidated)**
	OPINION

CECCHI, District Judge.

I. INTRODUCTION

This matter comes before the Court upon application of Plaintiff Biogen Idec MA Inc. ("Biogen") and Defendants EMD Serono, Inc. ("Serono"), Pfizer Inc. ("Pfizer"), Novartis Pharmaceuticals Corp. ("Novartis"), and Bayer HealthCare Pharmaceuticals, Inc. ("Bayer") (collectively, "Defendants") for claim construction pursuant to Local Patent Rule 4.5. The parties seek the Court's interpretation of a claim in United States Patent No. 7,588,755 (the "'755 Patent"). The parties presented their arguments at a Markman hearing. Having considered the parties' written submissions and oral arguments, including additional briefing subsequent to the Markman hearing, the Court sets forth its construction of the claim below.

II. FACTUAL BACKGROUND

The '755 Patent claims a method for immunomodulation, or treating viral diseases, cancers, or tumors, by administering to a patient a recombinant polypeptide—human interferon beta or "HuIFN-β"—that is produced by a non-human host transformed by a recombinant DNA molecule.

By way of background, the interferon relevant to this action is a "small, acid stable (glyco)-protein[] that render[s] cells resistant to viral infection." ('755 Patent at 1:39-40.) "Human

interferon has been classified into three groups α, β and γ," (*id.* at 1:49-50), and is produced in "diploid fibroblast cells" and "in minor amounts . . . in lymphoblastoid cells." (*Id.* at 1:50-53.) "[Hu]IFN-β is usually not detectable in normal or healthy cells." (*Id.* at 2:40.) Instead, "the protein is produced as a result of the cell's exposure to an IFN inducer." (*Id.* at 2:41-42.) Such IFN-inducers "are usually viruses but may also be non-viral in character, such as natural or synthetic double-stranded RNA, intra-cellular microbes, microbial products and various chemical agents." (*Id.* at 2:43-46.)

"Interferon therapy against viruses and tumors or cancers has been conducted," (*id.* at 2:53-54), and "in addition to its use as an antiviral agent, HuIFN-β has potential application in antitumor and, anticancer therapy." (*Id.* at 3:57-59.) "However, large-scale use of IFN as an antiviral agent requires larger amounts of IFN" than previously available. (*Id.* at 3:14-16.) Specifically, human IFN-β "produced by human cell lines grown in tissue culture" resulted in a "low yield, expensive process." (*Id.* at 4:49-50.) This problem was eventually solved by

> locating and separating DNA sequences that code for the expression of HuIFN-β in an appropriate host thereby providing DNA sequences, recombinant DNA molecule and methods by which a host is transferred to produce a polypeptide displaying an immunological or biological activity of human fibroblast interferon.

(*Id.* at 6:48-53.) By virtue of this discovery, it was "possible to obtain polypeptides displaying an immunological or biological activity of HuIFN-β for use in antiviral, antitumor or anticancer agents and methods." (*Id.* at 6:54-59.)

III. PROCEDURAL BACKGROUND

All parties in this litigation manufacture, import, and/or sell or offer to sell recombinant IFN-β products approved by the United States Food and Drug Administration ("FDA") for the treatment of multiple sclerosis via immunomodulation. Biogen's product is AVONEX®; EMD Serono's and Pfizer's product is REBIF®; Bayer's products are BETASERON® and

EXTAVIA®; and Novartis's product is EXTAVIA®.

On May 27, 2010, Bayer filed suit against Biogen seeking a declaration that Bayer does not infringe the '755 Patent and that the '755 Patent is invalid. On May 28, 2010, Biogen filed suit against EMD Serono, Pfizer, Bayer, and Novartis. Biogen asserts (1) EMD Serono and Pfizer infringe claims 1-3 of the '755 Patent by making, using, selling, and/or offering to sell REBIF®, (2) Bayer infringes claim 1 of the '755 Patent by making, using, selling, and/or offering to sell BETASERON® and EXTAVIA®, and (3) Novartis infringes claim 1 of the '755 Patent by selling and/or offering to sell EXTAVIA®. Defendants claim that the '755 Patent is invalid, not infringed, and/or unenforceable. The lawsuits were consolidated on October 1, 2010.

IV. LEGAL STANDARD

Claim construction is a matter of law for the Court to decide. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

The Court begins a claim construction analysis by examining the intrinsic evidence, which includes the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). If the claim term remains unclear or ambiguous after examining the intrinsic evidence, the Court may turn to extrinsic evidence, *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216 (Fed. Cir. 1995), which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995).

"A claim construction analysis must begin and remain centered on the claim language itself." *Innova*, 381 F.3d at 1116. "[I]t is that language that the patentee chose to use to particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention." *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (internal quotation marks omitted). The claims themselves and the context in which a term is used within the claims can "provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. In addition, other claims of the patent may be useful in construing a claim term, as "claim terms are normally used consistently throughout the patent." *Id.* Similarly, claims that differ from each other may provide insight into how a term should be read. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991).

"The claims, of course, do not stand alone. Rather, they are part of a fully integrated written instrument" called the "specification." *Phillips*, 415 F.3d at 1315. The Federal Circuit has said that "claims must be read in view of the specification." *Markman*, 52 F.3d at 978. For this reason, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582. Therefore, after examining the claims, "it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Id.* "For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." *Markman*, 52 F.3d at 979.

Finally, the Court should also examine the prosecution history. *Phillips*, 415 F.3d at 1317. The prosecution history is the complete record of the proceedings before the United States Patent and Trademark Office ("USPTO"), and "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the

invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id*; *see also Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013) (noting that the district court was correct in relying on prosecution statements when the specification contained no reference to the disputed term).

There is a heavy presumption that a claim term conveys its ordinary and customary meaning, which "is the meaning that the term would have to a person of ordinary skill in the art[1] in question at the time of the invention." *Phillips*, 415 F.3d at 1313. But a patentee may overcome this presumption and choose "to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term." *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999); *see also Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000); *Markman*, 52 F.3d at 979-80.

"[I]deally there should be no 'ambiguity' in claim language to one of ordinary skill in the art that would require resort to evidence outside the specification and prosecution history." *Markman*, 52 F.3d at 986. However, if there remains ambiguity, the Court may consult extrinsic evidence. Extrinsic evidence is generally "less significant than the intrinsic record in determining the legally operative meaning of disputed claim language." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quotations omitted). In addition, extrinsic evidence ordinarily should not contradict intrinsic evidence. *Phillips*, 415 F.3d at 1322-23. Therefore, extrinsic evidence must be viewed within the context of intrinsic evidence. *Id.* at 1319.

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[1] In this Opinion, the Court will refer to a person of ordinary skill in the art as a "POSA." This term includes all iterations of this concept, such as "a person having ordinary skill in the art," "one of ordinary skill in the art," etcetera.

Consistent with the law of claim construction as discussed above, this Court will first look to the language of the disputed claim term itself in the context of the claim in which it appears as well as the other claims in the patent. The Court will then look to the patent specification and read the claim in view of the specification. Next, the Court will look to the prosecution history to determine whether and how the patentee understood the invention. Finally, to the extent necessary, the Court will look to the extrinsic evidence (such as expert declarations) to resolve any remaining ambiguities. The Court will view the expert declarations within the context of the intrinsic evidence.

V. DISCUSSION

The relevant claim for the Court's consideration is claim 1, which reads (with the disputed claim language emphasized):

> A method for immunomodulation or treating a viral conditions[*sic*], a viral disease, cancers or tumors comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of a composition comprising: a recombinant polypeptide ***produced by a non-human host transformed by a recombinant DNA molecule*** compromising a DNA sequence selected from the group [identified in the claim].

A. Technical Meaning

The Court must determine the technical meaning of the term "produced by a non-human host transformed by a recombinant DNA molecule." Plaintiff Biogen and Defendants Bayer and Novartis agree that this term means "expressed by a transformed cell line that is not a human cell line, wherein a recombinant DNA molecule was/is incorporated into a cell such that it remains stably and non-transiently present in the cell, but does not necessarily need to be incorporated into the chromosome of the cell, wherein the incorporation typically occurs once and does not occur when a cell reproduces through the natural process of cell division." (ECF No. 179.)

It is unclear whether Defendants Pfizer and Serono agree with this proposed meaning. At the claim construction hearing, Pfizer and Serono stated that they "agree fundamentally on what it means to transform a host cell with a recombinant polypeptide and to produce a recombinant polypeptide from a transformed cell . . . ." (Tr. 31:12-15.[2]) Thereafter, given remaining questions as to the parties' theories and the status of Pfizer and Serono's position, the Court instructed each side to submit a brief "summarizing its final position on claim construction." (ECF Nos. 179, 233.) Defendants' joint brief did not appear to contain any mention of a dispute regarding the technical meaning. (ECF No. 240.)

To the extent there is a dispute, it involves two issues: (1) whether the "non-human host" is limited to one cell or includes the entire cell line; and (2) whether transformation requires incorporation into the host cell's genome. The Court finds Biogen, Bayer, and Novartis's agreed meaning to be consistent with the way a POSA would understand the claim term in the context of recombinant DNA technology.

As to the first issue, consistent with Biogen, Bayer, and Novartis's agreed meaning, a POSA would understand that "non-human host" refers to the transformed cell line rather than the individual transformed cell. (ECF No. 113 at 15.) In fact, a POSA would recognize that individual cells are transformed specifically so they will replicate in growth culture media to generate billions of identical cells (*i.e.*, the cell line) that produce enough recombinant polypeptide to treat patients. (*Id.* at 16.)

As to the second issue, a POSA would understand from the context of the patent that the transformation of the host cell does not require incorporation into the host cell's genome. Rather,

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[2] "Tr." refers to the transcript of the claim construction hearing, ECF No. 203.

it only requires the introduction of the recombinant DNA molecule into the host cell in a stable non-transient manner. The specification discusses only "insert[ing]" or "plac[ing]" the recombinant DNA into the cell. *See, e.g.*, '755 patent at 9:16-19. A POSA would recognize that the objective of transforming the host cell is to generate recombinant polypeptides in a cell line, which is achieved by introducing the recombinant DNA into the host cell in a stable non-transient manner. Accordingly, Biogen, Bayer, and Novartis's agreed meaning is consistent with the way a POSA would understand the claim term.

B. Scope

The issue before the Court pertains to the scope of claim 1. Specifically, the dispute concerns the nature of the words "produced by" and "transformed by" in the claim language. Defendants contend these two terms are separate steps in the claim. Biogen argues that Defendants' contention does not present an issue of claim construction for the Court to decide at this time. Alternatively, Biogen argues that the words "produced by" and "transformed by" are not separate steps in the claim.

1. The scope of the claim is an issue of claim construction.

Biogen argues that this dispute over the "scope" of the claim language is an issue of the burden of proof for infringement and, therefore, it is inappropriate for the Court to resolve at the claim construction stage of the case. Defendants contend this is an issue of claim construction appropriately decided by the Court at this time. For the reasons that follow, the Court agrees with Defendants.

The law is clear that patent infringement analysis involves two separate steps: "First, the court determines the scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device." *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998). Biogen argues that at the first step (the claim

construction step), the Court should only determine the technical meaning of the claim term but not the scope. That argument, however, contravenes the Federal Circuit's explicit instructions to determine both the "***scope and*** meaning." *Id.*

As part of the claim construction process, courts are routinely tasked with making determinations that are not strictly limited to the technical meaning of claim terms and limitations. *See, e.g.*, *Inventio AG v. Thyssenkrupp Elevator Ams. Corp.*, 649 F.3d 1350, 1356 (Fed. Cir. 2011) (treating the question of whether a limitation is a "means plus function" limitation as a claim construction issue); *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358-59 (Fed. Cir. 2010) (treating the question of whether the preamble is a limitation as a claim construction issue); *Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1377-78 (Fed. Cir. 2009) (determining, as a matter of claim construction, that a certain characteristic was "a structural attribute possessed by the claimed frame and is not a process limitation"); *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005) (treating the issue of whether a "whereby" clause is a limitation as a claim construction issue). The disputed issue in this case—whether the claim should be treated as a multi-step method—fits squarely within the claim construction framework.

Biogen seeks to classify the dispute over the scope of claim 1 as part of the second step of the patent infringement analysis. Accordingly, Biogen contends it is an issue to be determined at trial. Defendants, however, correctly point out that determining the scope of claim 1 does not require the court to compare the claim to any allegedly infringing product. (Defs. Opening Br. at 8, ECF No. 119-1.) Biogen's citations to case law only confirm this conclusion, as each case describes the second step of the infringement analysis as a comparison of the claim to the accused product. (*See* Biogen Opening Br. at 24, ECF No. 113.) Furthermore, in a case concerning similar technology, the Federal Circuit, "as a matter of claim construction" affirmed a district court's

determination that the language "purified from mammalian cells grown in a culture" was a source limitation on the product. *See Amgen Inc. v. F. Hoffman-La Roche, Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009).[3] Accordingly, the dispute over the scope of the claim term in this case is a claim construction issue.

2. The terms "produced by" and "transformed by" are not method steps.

Defendants argue that the terms "produced by" and "transformed by" introduce distinct steps of the claim. Accordingly, Defendants contend that claim 1 recites three steps: (1) transforming the non-human host; (2) producing the recombinant HuIFN-β; and (3) administering to a patient in need the HuIFN-β. Under Defendants' proposed construction, to be liable for patent infringement, an accused infringer must perform all three steps—transforming, producing, and administering—in the United States during the term of the patent.

In contrast, Biogen argues that claim 1 recites a single-step method that includes only the step of "administering" the recombinant HuIFN-β to a patient. Biogen argues that the terms "produced by" and "transformed by" merely describe characteristics of the recombinant HuIFN-β that is to be administered. Under Biogen's construction, it is irrelevant to the infringement analysis who performed the intermediate processes of producing and transforming and when those processes were performed. Rather, according to Biogen, the only issue is whether those intermediate processes were performed at some point prior to the "administering" step (which is the only affirmative step in the method claim, and thus the only method step that must be performed during the patent term to infringe the claim). For the reasons that follow, this Court agrees with

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[3] The Court recognizes that the claim at issue in *Amgen* was a product claim, not a method claim as here. However, despite this distinction, the Court finds it instructive that the question was determined as a matter of claim construction.

Biogen that claim 1 recites a one-step method of "administering" the recombinant HuIFN-β to a patient.

a) Claim Language

The Court looks first to the plain language of the claim. *See Vitronics*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("First, we look to the words of the claims themselves . . . to define the scope of the patented invention."). The claim reads as a single-step method:

> ***A method*** for immunomodulation or treating a viral conditions[*sic*], a viral disease, cancers or tumors ***comprising the step of administering*** to a patient in need of such treatment a therapeutically effective amount of a composition ***comprising:***
> a recombinant polypeptide ***produced by*** a non-human host ***transformed by*** a recombinant DNA molecule comprising a DNA sequence selected from the group consisting of:
> (a) DNA sequences which are capable of hybridizing to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793) under hybridizing conditions of 0.75 M NaCl at 68° C. and washing conditions of 0.3 M NaCl at 68° C., and which code for a polypeptide displaying antiviral activity, and (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);
> said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

'755 Patent, claim 1 (emphasis added). The word "step" in the claim is singular, not plural. The "step" it describes is written in the present tense—"administering." And this administering step is separated grammatically by a colon from the description of the recombinant polypeptide.

The plain language of the remainder of the claim does not state two additional affirmative steps that must be performed. Rather, it describes the recombinant polypeptide that is administered to practice the claimed invention—it must have been produced by a non-human host that was transformed by a recombinant DNA molecule coding for HuIFN-β. Thus, a natural reading of the claim supports a construction that requires only a single method step.

Defendants argue that "[b]ecause '***produced***' can only be interpreted in this context as the past tense of the verb 'produce,' it conveys something that ***must be*** done . . . ." (ECF No. 119-1 at 11 (emphasis added).) This argument is internally inconsistent because it conflates tenses. It ignores the more appropriate way of interpreting the word "produced" as describing what "must have been" done rather than what "must be" done. Moreover, it does not explain why the word "produced" signifies a multi-step process rather than merely a description of the recombinant polypeptide required to perform the method claim.

Defendants make two other arguments regarding the claim language. First, Defendants argue that the Federal Circuit decision in *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352 (Fed. Cir. 2007) compels a reading of the terms "produced" and "transformed" as additional and separate steps. Second, Defendants argue that the claim should be treated as a product-by-process claim,[4] such that "produced" and "transformed" are discrete steps that must be shown to prove infringement. Neither of these arguments, however, persuades the Court to construe the claim as a multi-step method.

Regarding Defendants' argument based on *Monsanto*, that case is distinguishable. In *Monsanto*, the claim at issue was a dependent claim. Dependent claim 4 read: "[a] process comprising obtaining progeny from a fertile transgenic plant ***obtained by the process of claim 1*** which comprise said DNA." *Id.* at 1355 (emphasis added). The claim from which it depended, independent claim 1, recited a three-step method for producing a transgenic corn plant. *Id.* at 1357. The Federal Circuit determined that because the defendant did not perform the three steps in

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[4] "A product-by-process claim is one in which the product is defined at least in part in terms of the method or process by which it is made." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006) (internal quotation marks and citations omitted).

independent claim 1 (*i.e.*, the steps required to produce the transgenic corn plant), it necessarily did not infringe claim 4 (*i.e.*, the method of obtaining progeny from that transgenic corn plant). The court held that claim 4 was "dependent from claim 1 because it only stands if all three steps recited in claim 1 have been performed. In other words, the additional fourth step of obtaining progeny depends on the performance of the process comprising the three steps recited in claim 1 for obtaining a fertile transgenic plant." *Id.* at 1358.

Monsanto is distinguishable from this case because the Federal Circuit determined that claim 4 in *Monsanto* was a ***dependent*** claim.[5] A dependent claim necessarily includes the limitations of the claim from which it depends. *See* 35 U.S.C § 112, ¶ 4 (2000) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."); *see also Monsanto*, 503 F.3d at 1358 ("Claim 4 thus incorporates the format specified by the statute for ***dependent*** claims. Contrary to Monsanto's argument, claim 4 ***clearly references*** another claim, not simply a starting material." (emphasis added)). In *Monsanto*, it was undisputed that the relevant independent claim contained three method steps that, in order to infringe, had to be performed during the term of the patent. Thus, upon the *Monsanto* court's determination that claim 4 was a dependent claim, those three method steps were necessarily incorporated into dependent claim 4. Here, claim 1 of the '755 Patent is an independent, not a dependent, claim. Unlike claim 4 in

[5] Defendants argue this is "not a relevant distinction between the claim in *Monsanto* and the claims in this case." (Defs. Supplemental Brief at 6 n.5, ECF No. 240.) To the contrary, for the reasons that follow, the Court finds this to be a highly relevant distinction.

Monsanto, there is no language in claim 1 of the '755 Patent that directly incorporates additional method steps from another claim. *Id.*

The Court is also not persuaded by Defendants' product-by-process claim argument. Defendants argue that the claim before the Court should be treated like a product-by-process claim, and that the words "produced" and "transformed" be construed as separate steps that must be shown in addition to "administering" to prove infringement. Thus, Defendants ask this Court to conclude that Biogen will have to prove that the accused infringer "produced," "transformed," and "administered" the recombinant polypeptide during the term of the patent.

First, it is unclear that this method of treatment claim can be treated as a product-by-process claim. Product-by-process claims "are always to a product, not a process." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 (Fed. Cir. 2006). The Court is aware of no binding precedent requiring method of treatment claims to be treated as product-by-process claims in the claim construction context.

Second, even if the product-by-process analogy were adopted, it does not support Defendants' position that the claim contains three steps that must be performed by the accused infringer in the United States during the term of the patent. To the contrary, cases have held that to infringe a product-by-process claim, there is only a requirement that the process be performed by someone somewhere at some time. *See Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 836, 840 n.4 (Fed. Cir. 1992) (retailer infringed product-by-process claim by selling product made by another company); *see also McAirlaids, Inc. v. Kimberly-Clark Corp.*, No. 7:13-cv-193, 2013 U.S. Dist. LEXIS 181611, at *8 (W.D. Va. Dec. 31, 2013) ("Nothing in the clear language of § 271(a) requires the process steps of a product-by-process claim to occur in the United States as an element of infringement. Nor has any case so held."). Accordingly, this claim contains one

method step—"administering"—which Biogen will have to prove was performed by the accused infringer in the United States during the term of the patent. As for the "produced" and "transformed" limitations, they are merely descriptive of the recombinant polypeptide to be administered.

b) Specification

In support of their proposed construction, Defendants point to the specification's extensive discussion of how the recombinant polypeptide is made. However, the fact that the specification also contains a description of the transformation of non-human hosts and the production of the recombinant polypeptide does not detract from the plain language of the claim itself, which refers only to a single-step method. Nor does the description of the transformation and production methods require that claim 1 be limited to include additional steps. *See Phillips*, 415 F.3d at 1323 (cautioning against importing limitations from the specification into the claims).

Moreover, the specification makes clear that the use of the recombinant polypeptide in methods of treatment is an object of the invention, independent of the method for making the recombinant polypeptide. *See* '755 Patent at 1:24-28 ("As will be appreciated from the disclosure to follow, the DNA sequences, recombinant DNA molecules and processes of this invention may be used in the production of polypeptides useful in antiviral and antitumor or anticancer agents and methods and in immunomodulation."); *id.* at 6:54-59 ("By virtue of this invention, it is possible to obtain polypeptides displaying an immunological or biological activity of HuIFN-β for use in antiviral, antitumor, or anticancer agents and methods."). Thus, the specification is

consistent with a construction of the claim as a single-step method of administering the recombinant polypeptide.[6]

c) Prosecution History

Defendants cite the prosecution history of the '755 Patent, and specifically the examiner's and Biogen's use of the plural term "steps" during prosecution. (*See* ECF No. 119-1 at 15; ECF No. 240 at 8-10; ECF No. 148 at 7-15.) Biogen responds that the statements made by the examiner and the applicant were in reference to a single step in multiple claims—not multiple steps in a single claim. (ECF No. 145 at 5.) Biogen also notes that certain of the claims at issue in these communications with the examiner did not actually contain the "produced" or "transformed" language and, therefore, the "produced" and "transformed" terms could not have been the "steps" referred to during prosecution. (Biogen Claim Construction Position Summary at 10-13, ECF No. 237; ECF No. 145 at 4-10.) Biogen further argues that the amendments make clear that "administering" was the only step contained in the differing claims, and any reference to "steps" within a single claim was an inadvertent mistake. (*Id.*)

Based on the ambiguities in the prosecution history, the Court finds the passages cited by Defendants insufficient to require three separate method steps in claim 1. This is especially true given the actual language of the claim, which supports a single-step method. Moreover, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and

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[6] The Court notes Defendants' argument that the process for making the recombinant polypeptide is the only thing that distinguishes the claim from the prior art. (*See* ECF No. 148 at 18.) However, as that argument is directed to invalidity rather than claim construction, the Court will not consider it at this time. *See Generation II Orthotics, Inc. v. Med. Tech., Inc.*, 263 F.3d 1356, 1365 (Fed. Cir. 2001) (only allowing claims to be construed to preserve validity in limited contexts).

thus is less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317; *see also Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1380-82 (Fed. Cir. 2002) (finding that the ambiguity of the prosecution history made it less relevant to claim construction); *Athletic Alts., Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1580 (Fed. Cir. 1996) (explaining that the ambiguity of the prosecution history made it "unhelpful as an interpretive resource" for claim construction).[7]

d) Extrinsic Evidence

The Court finds the intrinsic evidence sufficient to support its construction. However, in the interest of thoroughness, the Court notes that during an arbitration between Biogen and EMD Serono, the three-arbitrator panel described the '755 Patent as claiming a "single-step process consisting of administering beta interferon produced by a non-human host." *Ares Trading S.A. v. Biogen Idec MA, Inc.*, Case No. CPR G-11-16 (2012), Final Award ¶ 16. Thus, the most compelling piece of extrinsic evidence supports the Court's construction of the claim as a single-step method.

VI. CONCLUSION

The Court, in accordance with the discussion above, has construed claim 1 of the '755 Patent. The scope of the claim is limited to a one-step method of "administering" to a patient in need the specified recombinant HuIFN-β.

The term "produced in a non-human host transformed by a recombinant DNA molecule" is construed to mean "expressed by a transformed cell line that is not a human cell line, wherein a recombinant DNA molecule was/is incorporated into a cell such that it remains stably and non-

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[7] Biogen also makes prosecution history arguments concerning a restriction requirement that suggested that the patent was directed to five different inventions. As this issue in the prosecution history is ambiguous, the Court does not rely on the restriction requirement for its construction of the disputed claim term.

transiently present in the cell, but does not necessarily need to be incorporated into the chromosome of the cell, wherein the incorporation typically occurs once and does not occur when a cell reproduces through the natural process of cell division."

An appropriate order accompanies this Opinion.

Dated: March 28, 2016

HON. CLAIRE C. CECCHI
United States District Judge